

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fischers Lane, room 1061
Rockville, MD 20852

July 13, 2005

Docket No. 2005D-0122

Comments on:
Draft Guidance for Industry, Investigators, and Reviewers
Exploratory IND Studies

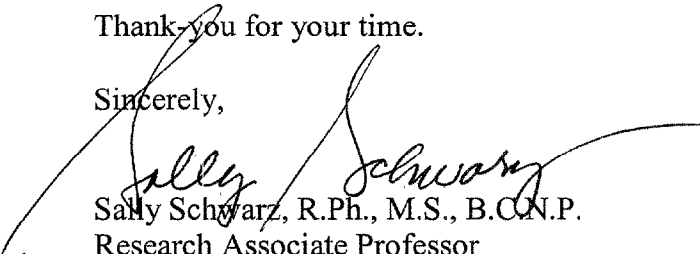
Dear Commissioner:

I want to say that I am pleased the FDA is moving in the direction of making the IND process less cumbersome, and hopefully this will expedite the overall timeline for submission and review.

I do have several question/comments relating to Page 9 of the Draft Guidance, lines 317-332. I would like the Extended Single-Dose Toxicity Studies clarified, and moved to a separate section which is presented prior to the clinical studies of pharmacokinetics or imaging. Within that section I would like clarification of what is meant in line 319 of... justified by in vitro metabolism data and by comparative data on in vitro pharmacodynamic effects. Possibly you could prepare a one-page information sheet similar to the August 1996 Guidance for Single Dose Acute Toxicity Testing for the draft Extended Single-Dose Toxicity Testing, or use the EMEA format of the "Position Paper on Non-Clinical Safety Studies to Support Clinical Trials with a Single Microdose" referenced in the FDA draft Guidance. This would help outline the steps required in the toxicity testing.

Thank you for your time.

Sincerely,


Sally Schwarz, R.Ph., M.S., B.C.N.P.
Research Associate Professor
Department of Radiology

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MIR Mallinckrodt Institute
of Radiology

510 South Kingshighway Boulevard, St. Louis, Missouri 63110, (314) 362-8435, Fax: (314) 362-9940

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